IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HORIZON PHARMA IRELAND LIMITED, HZNP LIMITED and HORIZON PHARMA USA, INC., *Plaintiffs,* v. ACTAVIS LABORATORIES UT, INC., *Defendant.*	C.A. Nos. 1:14-cv-07992-NLH-AMD (Consolidated with C.A. Nos. 15-5025, 15-6131, and 15-6989) Hon. Noel L. Hillman, U.S.D.J. Hon. Ann Marie Donio, U.S.M.J. [redacted] Motion Return Date: February 21, 2017

DEFENDANT ACTAVIS LABORATORIES UT, INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT OF U.S. PATENT NOS. 8,217,078, 8,546,450, AND 9,132,110

Liza M. Walsh
Christine I. Gannon
Katelyn O'Reilly
WALSH PIZZI O'REILLY FALANGA LLP
One Riverfront Plaza
1037 Raymond Blvd, Suite 600
Newark, NJ 07102
Telephone: (973) 757-1100

Ralph J. Gabric (admitted *pro hac vice*)
Mark H. Remus (admitted *pro hac vice*)
Laura A. Lydigsen (admitted *pro hac vice*)
Joshua E. Ney, Ph.D (admitted *pro hac vice*)
Joshua H. James (admitted *pro hac vice*)
Andrew S. McElligott (admitted *pro hac vice*)
BRINKS GILSON & LIONE
NBC Tower, Suite 3600
455 North Cityfront Plaza Drive
Chicago, Illinois 60611
Telephone: (312) 321-4200

Attorneys for Defendant Actavis Laboratories UT, Inc.

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I. INTRODUCTION

The facts here are simple, undisputed, and demonstrate that summary judgment of non-infringement of Horizon's method of treatment patents is appropriate. Each of the eight asserted claims in U.S. Pat. Nos. 8,271,078 ("the '078 patent"); 8,546,450 ("the '450 patent"); and 9,132,110 ("the '110 patent") at issue recites a method for treating osteoarthritis of the knee by applying both topical diclofenac sodium and a second topical substance, which must be either sunscreen, insect repellent, or a second topical medication. Horizon has failed to meet its burden to demonstrate facts sufficient to show infringement of these claims under 35 U.S.C. §§ 271(a), (b), or (c).

As a preliminary matter, there is no dispute that Actavis itself will not practice the claimed methods and thus will not directly infringe under 35 U.S.C. § 271(a).

Summary judgment is also appropriate for Horizon's inducement claims under 35 U.S.C. § 271(b), because Horizon has failed to make the requisite showing that Actavis has specific intent to induce patients to use Actavis's product with a second topical substance as required by the claims. The following two facts are undisputed and alone dictate a finding of no induced infringement:

- Actavis's Abbreviated New Drug Application ("ANDA") product will not be indicated for use with a second topical substance; and
- [redacted]

These undisputed facts alone negate any allegation that Actavis's labeling will "encourage, recommend, or promote" the use of a second topical as is required for induced infringement.

Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp., 785 F.3d 625, 631 (2015). Moreover, Horizon's expert also admitted: [redacted]; and that he failed to consider specific intent – a required element for induced infringement – in his analysis. Furthermore, neither Horizon nor its expert can identify a single instance in which a patient has practiced the claimed methods with Horizon's Pennsaid 2% product [redacted]

Finally, Horizon's allegations of contributory infringement under 35 U.S.C. § 271(c) consist of a few conclusory sentences in its contentions. Horizon fails to make the requisite showing that Actavis's ANDA product lacks substantial non-infringing use as is required for contributory infringement. Indeed, Horizon's expert has admitted just the opposite. Accordingly, summary judgment of no contributory infringement is likewise warranted.

II. BACKGROUND

A. Topical Diclofenac Sodium

This suit concerns Actavis's ANDA No. 207238, which pertains to diclofenac sodium topical solution 2% w/w [redacted] (SMF ¶¶ 75-76, 188.)[1] Diclofenac is a non-steroidal anti-inflammatory drug ("NSAID") that was first synthesized in 1973 and is available in varying concentrations in several topical pain medications, including Voltaren® (1%), Flector® (1.3%), Pennsaid® (1.5% & 2%), and

[1] "SMF" refers to Defendant's Local Civil Rule 56.1 Statement of Material Facts Not in Dispute in Support of Defendant's Motion for Partial Summary Judgment of Non-Infringement of U.S. Patent Nos. 8,546,450, 8,217,078, and 9,132,110 (hereinafter "the '450 Patent Family") submitted concurrently herewith pursuant to L. CIV. R. 56.1.

Solaraze® (3%). (SMF ¶ 80.) In above-captioned suit, Horizon alleges that Actavis's ANDA product will infringe five of the eighteen patents listed in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") in connection with Pennsaid® 2% w/w. (SMF ¶¶ 3-6, 13.)

B. Horizon's Patents

The patents-in-suit pertain to a diclofenac sodium topical formulation and methods for using such a formulation to treat pain associated with osteoarthritis ("OA") of the knee. (SMF ¶ 2.) The patents-in-suit fall into two patent families – the '838 formulation patent family and '450 method of treatment patent family. (SMF ¶ 7.) This motion involves only the latter, the '450 patent family.

Although Horizon has officially asserted over 56 claims of the four originally-asserted Orange Book-listed patents in the '450 family in this suit, Horizon has since dropped most of those allegations. (SMF ¶¶ 10-14.) At present, Horizon asserts infringement of eight claims from three patents in the '450 patent family: [redacted] All of these asserted claims recite methods for applying a topical diclofenac sodium formulation that contains dimethylsulfoxide ("DMSO") and subsequently applying a second topical substance "during the course of treatment" of osteoarthritis of the knee. (SMF ¶ 31.) [redacted]

For ease of reference, the relevant asserted independent claims of the '450 and '078 patents are reproduced below:

[redacted]

[redacted]

[redacted]

C. Horizon's Allegations That The Actavis ANDA Product Infringes

Horizon alleges that Actavis's ANDA product will infringe the eight asserted claims of its method patents. (SMF ¶¶ 11-12.) Although Horizon's contentions purport to allege that Actavis will directly infringe under 35 U.S.C. § 271(a) and contributorily infringe under 35 U.S.C. § 271(c) (SMF ¶¶ 11, 97), Horizon has provided no evidence to support these assertions and Horizon's expert, Dr. Marco Pappagallo, has conceded that Actavis does not infringe under these provisions. (SMF ¶¶ 96-99, 181-185.) Instead, Horizon has presented arguments that Actavis's labeling will induce infringement under 35 U.S.C. § 271(b). (SMF ¶¶ 117-142.)

1. ANDA Labeling Requirements

FDA regulations require that drug product labeling "must contain the specific information required under [21 C.F.R. §] 201.57(a), (b), and (c) under [particular] headings and

subheadings and in [particular] order." 21 C.F.R. § 201.56(d)(1). An ANDA must contain proposed labeling that is the "same as the labeling approved for the [reference] listed drug" subject to a handful of exceptions, e.g., revisions to reflect that the "new drug and the listed drug are produced or distributed by different manufacturers."[2] *See* 21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. §§ 314.127(a)(7), 314.94(a)(8)(iii)-(iv). Notwithstanding these exceptions, the FDA generally will not permit any deviation from the RLD labeling that may impact safety or efficacy. *See, e.g.*, *Hospira, Inc. v. Burwell*, No. 14-2662, 2014 U.S. Dist. Lexis 123972, at *20 (D. Md. Sept. 5, 2014) (noting FDA required showing that carve out of first indication would not "affect[ ] the safety and efficacy for the [second] indication from the label for Precedex®"). The FDA "interprets its regulations to require that the warning labels of a brand-name drug and its generic copy must always be the same—thus, generic manufacturers have an ongoing federal duty of 'sameness.'" *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011).

2. Actavis's Proposed Labeling

[redacted]

[2] Other exceptions exist for: (i) changes required to reflect the use of a "different active ingredient" or a "route of administration, dosage form, or strength [that] differ[s] from that of a listed drug" pursuant to a petition brought under 21 U.S.C. § 355(j)(2)(C); and (ii) changes required to reflect that the ANDA filer is not seeking approval for a particular indication pursuant to a carve-out under 21 U.S.C. § 355(j)(2)(A)(viii). *See* 21 C.F.R. § 314.94(a)(8)(iv). Neither exception is relevant in this case.

[redacted]

[redacted] are the sole support identified by Horizon's expert, Dr. Pappagallo, for Horizon's claim that Actavis will induce a patient to infringe the eight asserted method claims by applying a second topical substance. (SMF ¶¶ 121-122.)

III. LEGAL STANDARDS

A. Summary Judgment

A court properly grants summary judgment where "there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." *See* FED. R. CIV. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). Federal Rule of Civil Procedure 56 "mandates the entry of summary judgment . . . against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322-23.

B. Infringement Under 35 U.S.C. § 271

Horizon alleges that Actavis's filing of its ANDA No. 207238 constituted an artificial act of infringement under 35 U.S.C. § 271(e)(2). (Dkt. 1, Compl. ¶ 1.) "The proper inquiry under § 271(e)(2)(A) is 'whether, if a particular drug *were* put on the market, it *would* infringe the relevant patent[s].'" *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1366 (Fed. Cir. 2003) (emphases in original). As the patentee, Horizon bears the burden of proving by a preponderance of the evidence that Actavis's ANDA product would infringe its patents directly under 35 U.S.C. § 271(a) or indirectly under 35 U.S.C. §§ 271(b) or (c). *See Warner-Lambert*, 316 F.3d at 1366. This showing requires that Horizon demonstrate that "*every* step of the claimed method has been practiced." *Meyer Intellectual Props. Ltd. v. Bodum, Inc.*, 690 F.3d 1354, 1366 (Fed. Cir. 2012) (emphasis added).

1. Direct Infringement Under 35 U.S.C. § 271(a)

In order to demonstrate direct infringement under Section 271(a), a "patentee must either point to specific instances of direct infringement or show that the accused device necessarily infringes the patent in suit." *ACCO Brands, Inc. v. ABA Locks Mfr. Co.*, 501 F.3d 1307, 1313 (Fed. Cir. 2007).

2. Indirect Infringement Under 35 U.S.C. §§ 271(b) And (c)

Liability for indirect infringement under 35 U.S.C. §§ 271(b) and (c) requires a threshold showing of an underlying act of direct infringement. *See ACCO Brands*, 501 F.3d at 1312; *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1272 (Fed. Cir. 2004) ("Indirect infringement, whether inducement to infringe or contributory infringement, can only arise in the presence of direct infringement . . ."). This threshold showing requires proof of "specific instances of direct infringement or . . . that the accused [product] necessarily infringes the patent in suit." *ACCO Brands*, 501 F.3d at 1313. "[T]he patentee always has the burden to show direct

infringement for each instance of indirect infringement." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1303 (Fed. Cir. 2006).

a. Induced Infringement Under 35 U.S.C. § 271(b)

In addition to an underlying act of direct infringement, induced infringement under Section 271(b) further requires a showing that the accused infringer "induced infringing acts and that he knew or should have known his actions would induce actual infringements." *DSU*, 471 F.3d at 1304 (en banc in relevant part). "[M]ere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven." *Id*. at 1305 (en banc in relevant part); *Takeda*, 785 F.3d at 631 (2015). Thus, inducement requires both: (i) an active step to encourage infringement; and (ii) specific intent. *See DSU*, 471 F.3d at 1305 (en banc in relevant part); *Takeda*, 785 F.3d at 631; *Organon Inc. v. Teva Pharms., Inc.*, 244 F. Supp. 2d 370, 378-80 (D.N.J. 2002).

Knowledge that "acts might infringe" does not suffice for specific intent to induce infringement; instead, specific intent "requires proof the [accused infringer] knew the acts were infringing." *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1928 (2015). In the context of ANDA litigation, where allegations of inducement are based on labeling instructions, "such instructions must evidence 'intent to *encourage* infringement.'" *Takeda*, 785 F.3d at 631 (quoting *Vita-Mix Corp. v. Basic Holdings, Inc.*, 581 F.3d 1317, 1329 (Fed. Cir. 2009) (emphasis in original)). "[V]ague label language cannot be combined with speculation about how physicians may act to find inducement" as this "would seem to easily transform what [the Federal Circuit] ha[s] held is 'legally irrelevant,' *Warner-Lambert*, 316 F.3d at 1364 – mere knowledge of infringing uses – into induced infringement." *Takeda*, 785 F.3d at 632.

b. Contributory Infringement Under 35 U.S.C. § 271(c)

In order to establish contributory infringement under Section 271(c), Horizon must demonstrate that Actavis's ANDA product was "especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use . . . ." 35 U.S.C. § 271(c). "Substantial noninfringing uses" are those that are "not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Vita-Mix Corp.*, 581 F.3d at 1327. Summary judgment of no contributory infringement is appropriate where a product has substantial non-infringing uses. *See Dynacore Holdings Corp.*, 363 F.3d at 1277-78.

IV. ARGUMENT

A. There Is No Dispute That Actavis Itself Does Not Directly Infringe Under 35 U.S.C. § 271(a)

Summary judgment of no direct infringement is appropriate because Horizon fails to provide any argument or evidence to back up its naked assertion in its contentions of direct infringement under 35 U.S.C. § 271(a). (SMF ¶ 97.) Horizon makes no argument that Actavis itself – a pharmaceutical company – "treat[s] . . . patient[s] with combination therapy" or "appl[ies] topical agents to [the] knee[s] of . . . patient[s]," as required by all of the asserted claims of the '450 patent family. (SMF ¶¶ 17-18, 20, 27-30, 98.) The Federal Circuit has observed that "pharmaceutical companies do not generally treat diseases; rather, they sell drugs to wholesalers or pharmacists, who in turn sell the drugs to patients possessing prescriptions from physicians . . . . In none of these cases, . . . does the company itself *treat* the disease." *Warner-Lambert*, 316 F.3d at 1363 n.7 (emphasis in original). This holds true for Actavis.[3]

[redacted]

(SMF ¶ 77.) Horizon's infringement contentions allege only that the asserted method patents in the '450 family "would be directly infringed at least by users of Defendant's ANDA Product" – not that Actavis itself would directly infringe. (SMF ¶¶ 97-98.) Indeed, Horizon's expert in this case, Dr. Pappagallo, acknowledged that he was "[a]bsolutely not" contending that Actavis itself directly infringes Horizon's patents. (SMF ¶¶ 98-99.) As such, there is no dispute that Actavis itself does not directly infringe the asserted method claims of the '450 patent family, which require treating patients.

B. Horizon Has Failed To Present Facts Sufficient For The Requisite Underlying Act Of Direct Infringement

Summary judgment of no indirect infringement is appropriate because Horizon fails to meet its burden to demonstrate facts sufficient for the underlying act of direct infringement, which is required for a claim of indirect infringement under both 35 U.S.C. § 271(b) and § 271(c). *See ACCO Brands,* 501 F.3d at 1312. For each asserted method claim, Horizon makes no attempt to "point to specific instances of direct infringement or show that [Actavis's ANDA product] would necessarily infringe," as is required to survive summary judgment of non-infringement. *See id.* at 1313; *Otsuka Pharm. Co. v. Torrent Pharms. Ltd.*, 99 F. Supp. 3d 461, 469 (D.N.J. Apr. 16, 2015). Nothing suggests that any person will use Actavis's topical diclofenac sodium 2% with a second topical substance according to the method required by the asserted claims.

First, Horizon's infringement contentions make only a conclusory allegation that the second topical substance claims will be "directly infringed at least by users of Defendant's ANDA Product who use same as directed by Defendant's proposed label." (SMF ¶ 97.)

[redacted]

Second, Horizon's only expert testimony on infringement comes from Dr. Pappagallo. Dr. Pappagallo's opening report captures the flaw in Horizon's position. (SMF ¶¶ 100-101.) The entirety of Dr. Pappagallo's argument that use of Defendant's ANDA product will infringe the '450 method claims in his opening report is as follows:

[redacted]

Thus, Dr. Pappagallo asserts only that a POSA would not be inclined to apply a second topical substance absent statement(s) in Actavis's label. Conspicuously absent from Dr. Pappagallo's report is any assertion that patients ***will*** apply a second topical substance because of Actavis's label. (SMF ¶ 107.)

Third, the omission of any assertion of future direct infringement is unsurprising given Horizon's admissions that it is unaware of any person applying its own product, Pennsaid 2%, in

[redacted]

- Dr. Pappagallo acknowledged that he had no knowledge of whether any patient had ever applied a second topical:

> Q So you don't know whether any of those patients ever applied a second topical?
>
> A Yes. I don't know.

(SMF ¶¶ 114-116.) Given the lack of evidence suggesting any person has ever used Pennsaid 2% with a second topical substance in accordance with claimed methods, it is no wonder that Horizon and its expert make little effort to argue that physicians or patients will use Actavis's ANDA product in an infringing manner. Accordingly, summary judgment of non-infringement for both induced infringement and contributory infringement is appropriate due to Horizon's inability to allege that an underlying act of direct infringement will occur with respect to the second topical substance claims. *See ACCO*, 501 F.3d at 1312.

C. The Court Should Grant Summary Judgment Of No Induced Infringement Because Horizon Cannot Demonstrate Specific Intent To Encourage Infringement

Horizon premises its allegations of induced infringement for all of the asserted claims of the '450 patent family solely on Actavis's labeling. (SMF ¶¶ 121-122.) The content of the labeling is undisputed – and that content does not "encourage, recommend, or promote" the use of Actavis's ANDA product with other topical substances such as sunscreen, insect repellent or topical medications. *See Takeda*, 785 F.3d at 631 ("The label ***must*** encourage, recommend, or promote infringement." (emphasis added)). Summary judgment of no induced infringement is appropriate because Horizon has not (and cannot) meet its burden to show that Actavis's labeling "encourage[s], recommend[s], or promote[s] infringement" of any of the asserted method claims. *See id*.

1. It Is Undisputed That Actavis's ANDA Product Is Not Indicated For Use With Any Second Topical Substance

[redacted] Thus, it is undisputed that Actavis's proposed product will not be indicated for use in combination with any other drug. (SMF ¶¶ 92-94, 149-155.)

The Federal Circuit has repeatedly upheld summary judgment of no induced infringement in cases like this one in which the patented use is not an FDA-approved indication listed in the labeling of the accused infringer. *E.g.*, *Warner-Lambert*, 316 F.3d at 1352, 1364-65 (affirming grant of summary judgment of no induced infringement where the asserted patent covered only an unapproved use, i.e., treatment of neurodegenerative disease); *see also Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1323-24 (Fed. Cir. 2012) (upholding grant of summary judgment of no induced infringement where the patented method was not described in the label's Indications and Usage section and the label in its entirety did not otherwise recommend or suggest the use); *Allergan, Inc. v. Alcon Labs.*, 324 F.3d 1322, 1324 (Fed. Cir. 2003) (upholding summary judgment of noninfringement where ANDA filer sought approval for brimonidine for "reduction of intraocular pressure" but patents covered only use for "protecting the optic nerve" and "neural protection"). Likewise, summary judgment of no induced infringement is appropriate here.

While the Federal Circuit has occasionally found language in labeling outside the "Indications and Usage" section sufficient to induce infringement, such findings have been limited to cases where this language "would ***inevitably lead*** some consumers to practice the claimed method." *See, e.g.*, *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010) (emphasis added); *Eli Lilly & Co. v. Teva Parenteral Medicines*, No. 2015-2067, 2017 U.S. App. Lexis 555, at *23 (Fed. Cir. Jan. 12, 2017) (Ex.[4] 1). By contrast, nothing in Actavis's labeling encourages, recommends, or promotes a patient's [redacted]

[4] "Ex." refers to the corresponding exhibit attached to the Declaration of Andrew S. McElligott, filed concurrently herewith.

[redacted], let alone will "inevitably lead" to an infringing use.[5]

2. The Passages Of Actavis's Labeling On Which Horizon Relies Do Not "Encourage, Recommend, Or Promote" Applying A Second Topical Substance

[redacted] But none of these passages "encourages, recommends, or promotes" the application of a second topical substance as required for infringement of the asserted claims. *See Takeda*, 785 F.3d at 631.

[5] The District of Delaware's unpublished denial of declaratory judgment plaintiff IGI Laboratories, Inc.'s ("IGI") motion to dismiss the patentee's counterclaims alleging IGI's diclofenac sodium 1.5% product infringed the '078 and '450 patents has little bearing here. The District of Delaware focused on IGI's contention that *Bayer* alone precluded as a matter of law any claim for induced infringement because IGI's topical diclofenac sodium 1.5% product was not indicated for use with another topical substance. *IGI Labs., Inc. v. Mallinckrodt LLC*, No. 13-2044, 2014 U.S. Dist. Lexis 55520, at *6-7 (D. Del. Apr. 22, 2014). The court held only that "[w]ithout context, deciding this issue is inappropriate at the motion to dismiss stage" and that it would be improper to dismiss the patentee's counterclaims of infringement "at this juncture" given that they were "mirror images of IGI's declaratory judgment claims." *Id.* at *7-8. By contrast, this Court has a full record for "context" given that fact and expert discovery are complete and the current patentee, Horizon, brought the initial counts here.

[6] [redacted] Moreover, warnings are generally legally insufficient to induce infringement. *See United Therapeutics v. Sandoz, Inc.*, No. 12-cv-01617, 2014 WL 4259153, at *21 (D.N.J. Aug. 29, 2014) (holding "warnings in Sandoz's proposed label are not instructions").

a. Conditional Language In Actavis's Proposed Labeling Is Legally Insufficient For Intent To Encourage Infringement

[redacted]

These conditional statements do nothing to encourage a patient or doctor to apply a second topical substance in addition to Actavis's diclofenac sodium topical solution as is required for infringement of the asserted claims. These passages demonstrate that Actavis has no desire that patients apply another substance. As such, these passages are legally insufficient to evidence specific intent to induce infringement. *See Takeda*, 785 F.3d at 631.

[redacted]

It thus makes no sense that this passage should be read

as recommending, promoting, or encouraging the other listed topicals. In fact, Dr. Pappagallo admitted that the four passages are properly read as [redacted] He further acknowledged that these purported "instructions" only apply in the case of a patient's "medical need" for a second topical substance. (SMF ¶ 156.)

Courts have held similar neutral language in a generic's proposed labeling is insufficient to demonstrate specific intent to induce infringement. In *Shire v. Amneal Pharmaceuticals, LLC*, the court granted summary judgment of no induced infringement because a statement in the "Dosage and Administration" section that the drug "may be taken 'with or without food'" was insufficient to show intent to induce infringement of claims requiring administration with food. No. 11-3781, 2014 WL 2861430, at *4-5 (D.N.J. June 24, 2014), *aff'd in relevant part*, 802 F.3d 1301 (Fed. Cir. 2015). Like Actavis's labeling that recommends "nothing at all" (SMF ¶ 187), the *Shire* labeling was indifferent to which option was selected and thus did not evidence intent to induce infringement.

Similarly, the Federal Circuit held conditional language insufficient to establish the requisite specific intent for induced infringement in *Takeda*. 785 F.3d at 632. In *Takeda*, the accused drug product was indicated for the prophylaxis of gout and the labeling further instructed, "[i]f you have a gout flare, tell your healthcare provider." *Id*. The Federal Circuit rejected the patentee's argument that the label induced treatment of acute gout flares based on the instruction to "tell your healthcare provider," notwithstanding the patentee's physician declarations showing the likelihood that some prescribers would infringe the patent. *Id*. at 632-33. In holding Takeda's showing insufficient for induced infringement, the Federal Circuit reasoned, "[s]peculation, even proof that some, or even many, doctors would prescribe [the drug

product] for acute flares is hardly evidence of inevitability" and "does not show anything more than that there may be some infringing uses of [the drug product]." *Id*. at 633.

Finally, the non-infringing nature of the conditional statements in Actavis's labeling is confirmed by common sense. [redacted] Yet, incongruously, Dr. Pappagallo opines that similar cautionary, conditional language in Actavis's label would induce patients to take the actions cautioned against. Telling a person how to engage in an activity safely is not the same as telling a person to engage in the activity.

b. Warnings Do Not Encourage, Recommend, Or Promote The Application Of A Second Topical Substance

[redacted] Courts have repeatedly found such cautionary language "insufficient to constitute instruction or encouragement, as opposed to mere permission, and have consistently rejected safety discussions as a basis for inducement liability." *See Otsuka Pharm. Co.*, 99 F. Supp. 3d at 490 (collecting cases). [redacted]. Even Dr. Pappagallo reluctantly acknowledged that the passages constitute "warnings." (SMF ¶ 131.) [redacted]

[redacted]

Thus, there can be no dispute that these passages are cautionary in nature.

[redacted]

[redacted]

3. The Lack Of Intent To Induce Infringement Is Underscored By The Undisputed Fact That The Vast Majority Of Use Will Be Non-Infringing

Summary judgment of no induced infringement is appropriate "[e]specially where a product has substantial non-infringing uses, [because] intent to induce infringement cannot be inferred . . . ." *Vita-Mix Corp.*, 581 F.3d at 1329 (quoting *Warner-Lambert*, 581 F.3d at 1365). Here, Dr. Pappagallo does not dispute Dr. Zizic's opinion that the "Actavis ANDA Product, when used in accordance with the Actavis Labeling, will have substantial uses that will not infringe" claims requiring application of a second topical agent. (SMF ¶ 176.) Numerous studies, including one reported in the Actavis labeling itself, describe patients receiving topical diclofenac sodium alone – without the application of a second topical substance. (SMF ¶ 177.) Further, Dr. Zizic provided unrefuted testimony that the majority of patients who will be treated with Actavis's topical diclofenac sodium will receive Actavis's ANDA product alone or in combination with non-pharmacological remedies such as physical therapy, exercise, or braces or non-topicals such as acetaminophen, nutraceuticals, intra-articular corticosteroids, or hyaluronic acid injections - rather than a second topical substance. (SMF ¶¶ 178, 179.) Indeed, neither the word "staple" nor the phrase "noninfringing use" appear anywhere in either of Dr. Pappagallo's reports. (SMF ¶ 182.)

Moreover, Dr. Pappagallo admitted that many patients would not apply any of the three topical substances required by the claims [redacted] He acknowledged that the use of any other topical substance in conjunction with topical diclofenac sodium would only be "according to the needs of the patient obviously" and that those "needs" would occur only in a fraction of patients receiving Actavis's ANDA product. (SMF ¶¶ 158, 184-187.)

- [redacted]
- [redacted]

[8] [redacted]

[redacted]

Further, Dr. Pappagallo admitted that he has no knowledge as to whether any patient has ever used Pennsaid 2%, [redacted] in combination with a second topical agent. (SMF ¶¶ 114-116.)

The facts relating to substantial non-infringing use of Actavis's topical diclofenac sodium are similar to those that prompted summary judgment of no induced infringement of a patent requiring a combination of the ANDA product and a second medication called a selective serotonin reuptake inhibitor ("SSRI") in *Organon*. *See* 244 F. Supp. 2d at 382. In *Organon*, evidence that 23% of sales of the branded product were made in combination with an SSRI was insufficient to show intent to induce infringement. *Id*. at 381-82. Horizon's showing here is even weaker than the patentee's evidence in *Organon*; Horizon has failed to show that even one person has ever used Pennsaid 2% in conjunction with one of the other topical substances required by the claims in accordance with the claim limitations. Thus, summary judgment of no induced infringement is appropriate.

4. Dr. Pappagallo Admitted He Failed To Consider Specific Intent While Forming His Opinion That Actavis Will Induce Infringement

Even setting aside Dr. Pappagallo's admissions, his opinions that Actavis's labeling would induce infringement is unreliable and must be discounted because he did not consider the correct legal standard for induced infringement. *InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1348-1349 (Fed. Cir. 2014) (excluding opinion of expert for applying the wrong legal standard where the expert failed to consider objective evidence of nonobviousness). Specifically, Dr. Pappagallo acknowledged that he did not consider specific intent in forming his opinions of induced infringement:

Q: Did you consider Actavis' specific intent when you did your analysis here?

A: No, I didn't.

(SMF ¶¶ 159-160.) Contrary to well-established Supreme Court and Federal Circuit precedent, Dr. Pappagallo erroneously concluded that Actavis's labeling would induce infringement without considering specific intent. Instead, in his view, any act that might ultimately result in an infringement is inducement without regard for intent. But this is not the law. *See Commil USA, LLC v. Cisco Sys.*, 135 S. Ct. 1920, 1926-28 (2015) (holding that inducement "requires proof the defendant knew the acts were infringing."); *DSU*, 471 F.3d at 1306 ("[I]nducement requires evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct infringer's activities.").

Dr. Pappagallo's contention in his reply report that Actavis's obviousness position somehow conflicts with non-infringement misses the fact that knowledge of some potential infringing uses is legally insufficient for a showing of intent to induce infringement. *See Warner-Lambert*, 316 F.3d at 1364 ("[M]ere knowledge of possible infringement by others does not amount to inducement."). In fact, one court has found no inducement even in cases where 99.7% of the ANDA product's uses would be infringing. *See Novartis Pharms. Corp. v. Wockhardt USA LLC*, No. 12-cv-3967, 2013 U.S. Dist. Lexis 152141, at *28-31 (D.N.J. Oct. 23, 2013) (dismissing claim for induced infringement of patent for using the drug to treat osteoporosis where ANDA filer's label included only indication for Paget's disease notwithstanding "market reality" that 99.7% of use would be off-label for osteoporosis). Thus, the fact that it may have been obvious prior to 2009 to at least a few users of topical diclofenac sodium to practice the claimed method based on the teachings of the prior art Dimethaid monograph cannot salvage Horizon's legally deficient assertions of induced infringement.

D. Actavis Is Entitled To Summary Judgment Of No Contributory Infringement Given Its ANDA Product's Substantial Non-Infringing Uses

As noted above, there is no dispute that Actavis's topical diclofenac sodium topical solution will have substantial non-infringing uses: just as with Pennsaid 2%, the vast majority (if not all) users will not apply a second topical substance [redacted] along with Actavis's topical diclofenac sodium solution. (SMF ¶¶ 174-187; *see supra* IV.C.3.) Summary judgment is therefore appropriate because Horizon cannot demonstrate the absence of substantial non-infringing uses, as is required for a claim of contributory infringement under 35 U.S.C. § 271(c). *E.g.*, *Dynacore Holdings Corp.*, 363 F.3d at 1277-78 (affirming summary judgment of non-infringement under 35 U.S.C. § 271(c) where the accused "products are all capable of substantial non-infringing uses").

V. CONCLUSION

For the foregoing reasons, Actavis respectfully requests that the Court grant summary judgment of non-infringement of U.S. Patent Nos. 8,217,078, 8,546,450, and 9,132,110.

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WALSH PIZZI O'REILLY FALANGA LLP

s/ Liza M. Walsh

Liza M. Walsh
Christine I. Gannon
Katelyn O'Reilly
WALSH PIZZI O'REILLY FALANGA LLP
One Riverfront Plaza
1037 Raymond Blvd, Suite 600
Newark, NJ 07102
Telephone: (973) 757-1100

Ralph J. Gabric (admitted *pro hac vice*)
Mark H. Remus (admitted *pro hac vice*)
Laura A. Lydigsen (admitted *pro hac vice*)
Joshua E. Ney, Ph.D (admitted *pro hac vice*)

Joshua H. James (admitted *pro hac vice*)
Andrew S. McElligott (admitted *pro hac vice*)
BRINKS GILSON & LIONE
NBC Tower, Suite 3600
455 North Cityfront Plaza Drive
Chicago, Illinois 60611
Telephone: (312) 321-4200

Attorneys for Defendant Actavis Laboratories UT, Inc.